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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/194,396	12/08/98	HOLGERSSON J	4 [illegible]

HM12/0411

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EXAMINER	
EWOLDT, G	

ART UNIT	PAPER NUMBER
1641	7

DATE MAILED: 04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/194,396	Applica...(s) Holgersson et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Feb 22, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *15-19* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14 and 20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment, filed 2/22/00 (Paper No. 6) is acknowledged.

2. Applicant's election with traverse of Group I (claims 1-14 and 20) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that: Groups I and II are "indisputably" linked by a special technical feature, the relationships of Groups I and II are "invariably" found to be linked by a special technical feature, and that the principal ingredient of the invention of Group III is the invention of Group I. This is not found persuasive for the following reasons. As set forth in the previous Office Action the inventions of Groups I-III are patentably distinct for the reasons previously set forth, i.e., Groups I and II contain different products and Groups I and III are related as intermediate and final product. Additionally, as the Applicant stated, "the Examiner well knows, claims to proteins and the DNA encoding those proteins are routinely permitted in the same application." The Examiner also knows that while proteins and DNA's are "permitted" in the same application, they are routinely restricted to different groups.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 15-19 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-14 and 20 are being acted upon.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3 and 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) Claims 3, 7, 10-12, and 14 are indefinite in the recitation of "preferably" in that the metes and bounds of the claimed limitations are not clear.

B) Claims 8 and 11 are indefinite in the recitation of "essential part thereof" in that the metes and bounds of the claimed limitations are not clear.

C) Claims 9-14 are indefinite in the recitation of "immunoglobulin properties" in that the metes and bounds of the claimed limitations are not clear.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-4, 9-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) in view of U.S. Patent No 5,434,131 (1995).

Tsuji et al. teach an antigenic protein which carries multiple Galα(1,3)Gal epitopes, which is produced by a recombinant cell line, capable of binding antibodies to Galα(1,3)Gal epitopes (see particularly Results and Table 3).

The reference teaching differs from the claimed invention only in that recombinant protein is not a fusion protein.

The '131 patent teaches a fusion protein that includes a human IgFc domain, said IgFc domain added to provide a convenient "tag" for the purification of a fusion protein (see particularly column 10, Recovery of Protein Products).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare an antigenic protein with multiple Galα(1,3)Gal epitopes, as taught by Tsuji et al., fused to an IgFc region, as taught by the '131 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to produce the fusion protein because the IgFc region provides a convenient "tag" for the purification of said protein, as taught by the '131 patent. Claim 4 is included in the rejection because the source of the Galα(1,3)Gal transferase enzyme lends no patentable weight to the claimed product.

8. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) and U.S. Patent No 5,434,131 (1995) in further view of Sako et al. (1993)

Tsuji et al. and the '131 patent have been discussed supra. The combined reference teachings differ from the claimed invention only in that they do not teach PSGL-1 as the specific antigenic portion of the fusion protein.

Sako et al. teach the recombinant P-selectin binding protein PSGL-1 (see particularly Results).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare an antigenic protein with multiple Galα(1,3)Gal epitopes, as taught by Tsuji et al., using recombinant PSGL-1, as taught by Sako et al., fused to an IgFc region, as taught by the '131 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to produce the fusion protein using PSGL-1 as the antigenic portion of the protein because PSGL-1 is a mucin and mucins are well known to be highly glycosylated; thus PSGL-1 would be an obvious choice as an antigenic protein which carries multiple Galα(1,3)Gal epitopes to fuse with an IgFc domain.

9. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) in view of U.S. Patent No 5,434,131 (1995) as applied to claims 1-4, 9-11, and 13 above, and further in view of Goding (1983).

Tsuji et al. and the '131 patent have been discussed supra. The combined reference teachings differ from the claimed invention only in that they do not teach the use of a non-human, preferably mouse, IgG_{2b} Fc domain as the immunoglobulin part of the fusion protein.

Goding teaches that the IgG_{2b} Fc domain is one of a few Fc domains that could be used as a tag for purification of the fusion protein (see particularly page 117, Table 4.2)

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare antigenic proteins with multiple Galα(1,3)Gal epitopes, as taught by Tsuji et al., fused to IgG_{2b} Fc regions, as taught by the '131 patent and Goding. One of ordinary skill in the art at the time the invention was made would have been motivated to produce a fusion protein using the IgG_{2b} Fc domain because choosing from among the various obvious choices available (mouse, rat, etc.) of non-human Fc domains would allow for optimization of purification techniques. The choice between one of a few routinely used Fc domains that would allow for optimal purification of the protein are well within the purview of one of ordinary skill in the art at the time the invention was made and add no patentable weight.

10. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) in view of U.S. Patent No 5,434,131 (1995) and Sako et al. (1993) as applied to claims 1-11 above, and further in view of Goding (1983).

Tsuji et al. and the '131 patent and Sako et al. have been discussed supra. The combined reference teachings differ from the claimed invention only in that they do not teach the use of a non-human, preferably mouse, IgG_{2b} Fc domain as the immunoglobulin part of the fusion protein.

Goding teaches that the IgG_{2b} Fc domain is one of a few Fc domains that could be used as a tag for purification of the fusion protein (see particularly page 117, Table 4.2)

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare antigenic proteins with multiple Galα(1,3)Gal epitopes, as taught by Tsuji et al., using recombinant PSGL-1, as taught by Sako et al., fused to IgG_{2b} Fc regions, as taught by the '131 patent and Goding. One of ordinary skill in the art at the time the invention was made would have been motivated to produce a fusion protein using the IgG_{2b} Fc domain because choosing from among the various obvious choices available (mouse, rat, etc.) of non-human Fc domains would allow for optimization of purification techniques. The choice between one of a few routinely used Fc domains that would allow for optimal purification of the protein are well within the purview of one of ordinary skill in the art at the time the invention was made and add no patentable weight.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) and U.S. Patent No 5,434,131 (1995) in view of Kozlowski et al. (1997).

Tsuji et al. and the '131 patent have been discussed supra. The combined references differ from the claimed invention in that they do not teach the use of the fusion protein in a method for preventing a hyperacute rejection.

Kozlowski et al. teaches a method for preventing a hyperacute rejection of a xenotransplanted organ comprising bringing a xenotransplant patient's blood in contact with multiple Galα(1,3)Gal epitopes and thereafter reinfusing the blood to the patient (see entire document).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of removing Galα(1,3)Gal antibodies from a xenotransplant patient's blood, as taught by Kozlowski et al., using the fusion protein, as taught by Tsuji et al. and the '131 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to use the Galα(1,3)Gal-IgFc fusion protein to perform the claimed method because of its relative easy of purification, thus providing a convenient source of Galα(1,3)Gal epitopes.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald R. Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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April 7, 2000

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